K131306

II. 510(k) Summary

JUL 2 2 2013

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DATE:
May 23, 2013

DEVICEINFORMATION

DEVICE NAME:	IC-1545-DL Multi-Flo DVT Combo Intermittent Pneumatic Compression Device
Classification Panel:	Cardiological and Respiratory Devices
Classification Number:	870.5800
Product Nomenclature:	Compressible Limb Sleeve
Product Code(s):	JOW
Trade/Proprietary Name:	IC-1545-DL Multi-Flo DVT Combo
Common Name:	IC-1545-DL Multi-Flo DVT Combo Intermittent Circulator

DEVICECLASSIFICATION
Compressible Limb Sleeve Devices are classified as Class II devices, and reviewed by the Division of Cardiovascular Devices.

PREDICATEDEVICE
Model Multi-Flo IC-1545-KT/F Intermittent Circulator

DEVICEDESCRIPTION

The IC-1545-DL Multi-Flo DVT Combo (applicant device) provides intermittent pressure to the calf and thigh or foot through the use of inflatable garments. The applicant device is a digitally-controlled version of the predicate device, with identical specifications. There is no change in fundamental technology and no change in intended use from the predicate device, K610857. The digital modification provides identical calf/thigh (KT) and foot (F) timing and pressure options as the predicate and it has the same intended use as the predicate, including prophylaxis of deep vein thrombosis (DVT) and enhancing venous and arterial circulation. Tubing connector design variations prevent interchangeability of garments between the models.

The user interface consists of a soft keypad where the predicate has a rocker on/off switch and a pressure adjustment knob. The analogue pressure gauge and regulator have been removed, making the applicant unit 27% smaller and 47% lighter than the predicate, and both are designed to hang on bedrails for easy access to bed-ridden patients.

The device consists of a pump, inflatable garments, and interconnection tubing. The pump compressor is capable of no more than 150 mmHg maximum pressure and has pre-set inflate/deflate cycle times. Default pressure and timing is pre-set at the factory to 50 mmHg, with a cycle of 15 seconds on and 45 seconds off (KT option). This is consistent with the majority of indications prescribed.

All controls and measurement functions are contained in the PCB assembly. When turned on, the timer sends a signal to start the pump. The pump sends air to the output ports, filling the garments with air. A digital pressure sensor maintains the prescribed pressure by turning the compression pump on and off. After 45 seconds, the timer stops the pump and opens a valve to deflate the garments and 15 seconds later the cycle repeats.

In order to achieve its intended use, the device is attached via interconnecting tubing to sleeves (garments) applied externally and bilaterally over the lower extremities. The garments contain discrete, interconnected and segmented inflatable chambers. The pump provides intermittent, rapid impulse pressurization to the chambers. The pressure can be adjusted up or down in increments of 1 mmHg with up and down soft key arrows, and an alarm is provided for low/no pressure. When the garments are inflated, they compress the veins in the calf, expelling blood from the leg, overcoming blood stasis and promoting circulation.

The device runs continuously until turned off. An LED display shows the pressure setting during the inflation cycle and "0" during the deflation cycle. Pressure setting can be changed by the user, while timing cycles can be changed with special instructions provided to the distributor. An alarm will alert the user if inflation pressures do not exceed 30 mmHg.

All garments are supplied non-sterile and for single patient use. DVT prophylaxis garments are available in a total of three anatomical configurations as indicated to the calves or the calves and the thighs (KT) and the feet (F).

INDICATIONSFORUSE

When used with GID-3045-T Calf/Thigh or GID-3045-K Calf garments:

- ☐ Intended for prophylaxis of deep vein thrombosis

When used with GI-3045-F Foot Garments

- ☐ Intended for prophylaxis of deep vein thrombosis
- ☐ Enhancement of venous and arterial circulation

- ☐ Prevention of venous stasis ulcers
- ☐ Reduction of acute or chronic edema
- ☐ Reduction of lower limb pain due to surgery or trauma
- ☐ Reduction of compartment pressures

TECHNOLOGICALCHARACTERISTICS

The manufacturer believes that the technological characteristics of the modified IC-1545-DL Multi-Flo Combo device are substantially similar to those of the predicate IC-1545-KT and -F Multi-Flo devices. The user interface has been modified from a regulator and analogue dial gauge in the predicate to a digital pressure sensor and LED display in the applicant device. In place of a manual dial on a regulator in the predicate device, the pressure can be increased or decreased in increments of 1 mmHg via a soft keypad on the applicant device.

PERFORMANCEDATA

Before being released every device is tested and must meet all performance specifications. In addition to aesthetic acceptance criteria, functional testing includes electrical leakage, pressure adjustment, inflation pressure in each segment, air pressure display accuracy, and inflation/deflation cycle times. The results demonstrate comparable inflation cycle profiles (rise times, inflation pressures, deflation times and cycle times) between the applicant and predicate devices.

STATEMENTOFSUBSTANTIALEQUIVALENCE

Similarities

Both the applicant and the predicate devices provide continuous intermittent pneumatic pressure bilaterally to the foot, calf or calf and thighs using inflatable garments. The applicant and predicate devices have the same intended use and indications for use, both operate within the same clinically-established parameters and both have the same performance specifications. The applicant and predicate devices use the same prescribed inflation pressures, inflation and deflation times and cycle times.

Differences

The applicant device utilizes a digital pressure sensor and LED pressure display while the predicate device utilizes an analogue gauge and needle display. The applicant has soft key up and down arrows to adjust pressure up or down, accessible by pressing an access sequence on the soft keys, while the predicate device has a locking pressure control knob attached to a regulator.

Both the predicate and the applicant devices operate within the same clinically-established parameters. The differences between the predicate and the applicant devices do not impact safety or effectiveness. A table illustrating the similarities and differences is provided below.

Table of Similarities and Differences with the Predicate Device

Parameter	Predicate K061857 Models IC-1545-KT and -F	Digital IC-1545-DL-Multi Flo DVT Combo
Intended Use	KT and F: Prophylaxis of deep vein thrombosis. F: enhancement of venous and arterial circulation, prevention of venous stasis ulcers, assist in healing of cutaneous ulcers, reduction of acute or chronic edema, reduction of lower limb pain due to surgery or trauma, reduction of compartmental pressures.	Same
Principal of Operation	Intermittent Pneumatic Compression	Same
Weight	8 pounds	4.25 pounds
Dimensions, inches	5.5 H X 8 L X 12 W	6 H x 8 W x 8 D
# of Segments in garment(s)	1 - 4	Same
Inflation Time, each segment	15 seconds bilateral (KT) 6 seconds bilateral (F)	Same
Deflation Time	45 seconds(KT) 54 seconds (F)	Same
Recommended Inflation Pressure	45-60 mmHg (KT) 90-120 mmHg (F)	Same
Pressure Adjustment	Locking adjustable knob on regulator	Digital, soft keypad, 1mmHg increments
Pressure Gauge	0-125 mmHg, analog	0 - 120 mmHg, digital
Displayed Pressure Accuracy	± 5 mmHg of sleeve pressure, real time pressure displayed on gauge face	± 5 mmHg of sleeve pressure, pressure set point displayed on LED
Pause time between inflation cycles	None (deflation time is pause time)	Same
Total Cycle Time	60 seconds, 60 cycles per hour.	Same
Garments Available	Calf/thigh (Model KT) Foot (Model F)	Same
Fail-safe hose connectors	Yes	Yes
Bilateral Treatment Option	Yes	Yes
Power Requirements	120VAC, 60Hz, 0.5A	Same

CONCLUSION

Based upon safety and performance testing, compliance with voluntary standards, and comparison to the predicate devices, the manufacturer believes that the IC-1545-DL-Multi Flo DVT Combo Intermittent Pneumatic Compression Device is substantially equivalent to the predicate device, and does not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 11, 2014

Bio Compression Systems, Inc.
c/o Ms. Maureen Garner
1983 Hazelwood Road
Toms River, NJ 08753 US

Re: K131306
Trade/Device Name: IC 1545-DL Multi-Flow DVT Combo Intermittent Pneumatic Compression Device
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: May 23, 2013
Received: May 24, 2013

Dear Ms. Garner:

This letter corrects our substantially equivalent letter of July 22, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K131306

Device Names: IC-1545-DL Multi-Flo DVT Combo Intermittent Pneumatic Compression Device

Indications for Use:

When used with GID-3045-T Calf/Thigh or GID-3045-K Calf garments:

- Intended for prophylaxis of deep vein thrombosis

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- Prevention of venous stasis ulcers
- Reduction of acute or chronic edema
- Reduction of lower limb pain due to surgery or trauma
- Reduction of compartment pressures

Prescription Use (Part 21 CFR 801 Subpart D) X AND/OR Over-The-Counter Use (21 CFR 807 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)